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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,640	07/08/2003	Richard Merkin	MERKN-001A	1420

7590 12/31/2007
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EXAMINER

RANGREJ, SHEETAL

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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12/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/615,640

Applicant(s)

MERKIN, RICHARD

Examiner

Sheetal R. Rangrej

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,11-14,16-20,24-26 and 28-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 11-14, 16-20, 24-26, and 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Prosecution History Summary

1. Claims 1, 3-7, 11-14, 16-20, 24-26, and 28 are amended.
2. Claims 2, 8-10, 15, 21-23, and 27 are cancelled.
3. Claims 29-37 are new.
4. Claims 1, 3-7, 11-14, 16-20, 24-26, and 28-37 are pending.

DETAILED ACTION

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3-7, 11-14, 17-20, 24-26 and 29-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. (U.S. Patent No. 6,177,940) in view of Provost et al. (U.S. Patent No. 6,341,265) and further in view of Summerell et al (U.S. Patent No. 5,937,387).

7. As per claim 1, Bond teaches a method for administering health care to patients within a patient population such that utilization of health care resources available to care for said patients within said patient population are conserved, the method comprising the steps:

a) generating said patient population, said generation of said patient population comprising the steps:

i) receiving a request from an individual to become a patient within said patient population (**Bond: col. 10, 44-58**);

- ii) obtaining information from said individual in step (i), wherein said information is obtained by an in-person interview (Bond: col. 18, 37-40) wherein said information comprises demographic information, related to said individual comprising the individual's age, sex, medical history, and geographic vicinity pertaining to said individual's residence (Bond: col. 11, 11-24) as well as the number of emergency room visits, number of hospitalizations and readmissions, patient pharmacy records, and medication compliance (Bond: col. 11, 46-col. 12, 8; fig. 10A i.e. medical records);
- iii) evaluating said data submitted in step (ii) (Bond: col. 19, 21-42);
- iv) enrolling said individual as a patient within said patient population (Bond: fig. 9A; col. 10, 66-col. 11, 10); and
- v) repeating steps (i) - (iv) for a multiplicity of individuals (Bond: col. 10, 66-col. 11, 10). The examiner interprets that the steps can be repeated for many number of patients, who wish to be enrolled within the system;

Bond does not teach b) receiving a request from a patient within said patient population generated in step a) for medical services; c) assessing said request made in step b) and determining whether said request substantiates a specified clinical event, wherein said assessment is made by a primary care physician; d) submitting only a single CPT code corresponding to a single, specified medical service to be rendered in response to the clinical event specified in step (c); e) evaluating the single code submitted in step (d) for clinical and financial appropriateness, wherein said evaluation is performed by a hospitalist or case manager; and f) responding to said submission made in step (d) based upon said evaluation made in step

(e), said response comprising either approval or disapproval of the services to be rendered in relation to said code submitted in step (d).

Provost teaches b) receiving a request from a patient within said patient population generated in step a) for medical services (**Provost: figure 4A, 82**); c) assessing said request made in step b) and determining whether said request substantiates a specified clinical event (**Provost: figure 4A, 86**); d) submitting only a single CPT code corresponding to a single, specified medical service to be rendered in response to the clinical event specified in step (c) (**Provost: col. 6, 2-7** e) evaluating the single code submitted in step (d) for clinical and financial appropriateness, wherein said evaluation is performed by a hospitalist or case manager (**Provost: col. 6, 8-11**); f) responding to said submission made in step (d) based upon said evaluation made in step (e), said response comprising either approval or disapproval of the services to be rendered in relation to said code submitted in step (d) (**Provost: col. 6, 12-28**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond and Provost. One of ordinary skill would have been motivated to combine these teachings because over the years, the delivery of health care services has shifted from individual physicians to large managed health maintenance organizations and this shift gives more complexity to the already complex health care system. A careful review of payment requests minimizes fraud and unintentional errors and provides consistency of payment for the same treatment. (**Provost: col. 1, 14-38**)

Provost does not teach wherein is said assessment is made by a primary care physician.

Summerell teaches wherein said assessment is made by a primary care physician (**Summerell: col. 5, 45-52**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell. One of ordinary skill would have been motivated to combine these teachings because physicians help patients improve or maintain their conditions by providing them with helpful information (**Summerell: col. 5, 45-52**).

8. As per claim 3, the method of claim 1 is as described. Bond further teaches wherein in step (a), substep (iii), said evaluation comprises comparing said information submitted in step (a), substep (ii) with eligibility criteria, said eligibility criteria defining a standard by which said individuals are compared for acceptance as a patient within said patient population (**Bond: col. 19, 21-42**).

9. As per claim 4, the method of claim 1 is as described. Bond and Provost do not teach wherein in step (a), substep (iv), further comprises assigning a risk level to said patient.

Summerell teaches wherein in step (a), substep (iv), further comprises assigning a risk level to said patient (**Summerell: col. 4, 65 to col. 5, 18**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell. One of ordinary skill would have been motivated to combine these teachings because it provides a means to assess an individual's personal health habits and risk factors; estimate the individual's future risk of death, illness, or otherwise reduced quality of life, and provide counseling as to means of reducing this risk. These assessments take the form of mortality risk estimates and counseling phrases based upon relative risk. (**Summerell: col. 1, 43-50**)

10. As per claim 5, the method of claim 4 is as described. Bond and Provost do not teach wherein in step (a), substep (iv), said risk level assigned said patient is indicative of the anticipated utilization of resources said patient is projected to utilize while a member of said patient population.

Summerell teaches wherein in step (a), substep (iv), said risk level assigned said patient is indicative of the anticipated utilization of resources said patient is projected to utilize while a member of said patient population (**Summerell: col. 4, 15-29**)

The motivation to combine is the same as claim 4.

11. As per claim 6, the method of claim 3 is as described. Bond and Provost do not teach wherein in step (a), substep (iii), further comprises assessing the current state of health of said individual and anticipated future health of said individual by retrospectively examining the individual's prior medical history and prospectively examining the anticipated future medical needs of said individual.

Summerell teaches wherein in step (a), substep (iii), further comprises assessing the current state of health of said individual (**Summerell: col. 4, 20-25**) and anticipated future health of said individual by retrospectively examining the individual's prior medical history and prospectively examining the anticipated future medical needs of said individual (**Summerell: col. 3, 18-41**).

The motivation to combine is the same as claim 4.

12. As per claim 7, the method of claim 5 is as described. Bond and Provost do not teach wherein following step (a), substep (v), such process further comprises step:
(vi) periodically updating and reviewing information indicative of the health of said patients

within said patient population and reassigning risk levels associated with said patients within said patient population.

Summerell teaches wherein following step (a), substep (v), such process further comprises step: (vi) periodically updating and reviewing information indicative of the health of said patients within said patient population and reassigning risk levels associated with said patients within said patient population (**Summerell: col. 4, 42-64**).

The motivation to combine is the same as claim 4.

13. As per claim 11, the method of claim 1 is as described. Bond and Summerell do not teach wherein in step (f) further comprises the step of determining whether to provide a reimbursement to said primary care physician for said services sought to be rendered in relation to said code submitted in step (c).

Provost teaches wherein in step (f) further comprises the step of determining whether to provide a reimbursement to said primary care physician for said services sought to be rendered in relation to said code submitted in step (c) (**Provost: col. 11, 19-25**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell. One of ordinary skill would have been motivated to combine these teachings because over the years, the delivery of health care services has shifted from individual physicians to large managed health maintenance organizations and this shift gives more complexity to the already complex health care system. A careful review of payment requests minimizes fraud and unintentional errors and provides consistency of payment for the same treatment. (**Provost: col. 1, 14-38**)

14. As per claim 12, the method of claim 11 is as described. Bond and Summerell do not teach wherein in step (e), said evaluation of said code comprises reviewing said code submitted in step (d) to ensure against abusive billing practices.

Provost teaches wherein in step (e), said evaluation of said code comprises reviewing said code submitted in step (d) to ensure against abusive billing practices (**Provost: col. 10, 24-34**).

The motivation to combine is the same as claim 11.

15. For claim 13, please see citation and motivation of claim 12.

16. For claim 14, please see citations and remarks of claim 1. Repeating a method does not change the invention as a whole.

17. As per claim 17, the method of claim 5 is as described. Bond and Provost do not teach wherein step (a) substep (iv) further comprises the step of charging a premium to said individual for becoming a member of said patient population.

Summerell teaches wherein step (a) substep (iv) further comprises the step of charging a premium to said individual for becoming a member of said patient population (**Summerell: col. 4, 65 to col. 5, 18**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell. One of ordinary skill would have been motivated to combine these teachings because joining will provide an economic alliance of health care organizations, as well as individual organizations within the alliance, to more efficiently and effectively deliver health care goods and services under varying reimbursement arrangements, practice guidelines and health plan requirements (**Wiggins: col. 1, 46-52**).

18. As per claim 18, the method of claim 17 is as described. Bond and Provost do not teach wherein in said premium corresponds to said risk level assigned to said patient.

Summerell teaches wherein in said premium corresponds to said risk level assigned to said patient (**Summerell: col. 4, 65 to col. 5, 18**).

The motivation to combine is the same as claim 17.

19. As per claim 19, the method of claim 1 is as described. Bond and Summerell does not teach wherein in step (c), said code corresponds to a single medical service rendered exclusively by said physician.

Provost teaches wherein in step (c), said code corresponds to a single medical service rendered exclusively by said physician (**Provost: col. 9, 39-43; col. 9, 45-58**).

The motivation to combine is the same as claim 11.

20. For claim 20, please see citations and remarks of claim 1.

21. For claims 24-26, please see citations and remarks of claims 12-14, respectively.

22. As per claim 29, the method of claim 1 is as described. Bond further teaches wherein step (a), substep (ii), said number of emergency room visits and number of hospitalizations and readmissions are determined with respect to the twelve month period preceding obtaining the information (**Bond: col. 11, 46 – col. 12, 8; fig. 10A**). The examiner interprets that the information collected from patient regarding past medical history includes number of emergency room visits and number of hospitalizations and readmissions are determined with respect to the twelve month period preceding obtaining the information.

23. As per claim 30, the method of claim 1 is as described. Bond further teaches wherein step (a), substep (ii) further comprises obtaining information in relation to the current condition of any disease that said individual may have (**Bond: col. 13, 13-35**).

24. As per claim 31, the method of claim 30 is as described. Bond and Provost do not teach wherein the disease is hypertension.

Summerell teaches wherein said disease is hypertension (**Summerell: col. 13, 18-45**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell. One of ordinary skill in the art would have been motivated to combine these teachings because it allows for a better assessment of risk involving individuals (**Summerell: col. 3, 8-17**).

25. As per claim 32, the method of claim 30 is as described. Bond and Provost do not teach wherein the disease is diabetes.

Summerell teaches wherein said disease is diabetes (**Summerell: col. 13, 18-45**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell. One of ordinary skill in the art would have been motivated to combine these teachings because it allows for a better assessment of risk involving individuals (**Summerell: col. 3, 8-17**).

26. As per claim 33, the method of claim 7 is as described. Bond and Provost do not teach wherein said reassigning of risk levels is performed every six months.

Summerell does not explicitly teach wherein said reassigning of risk level is performed every six months, but does teach reassigning of risk level over a period of time (**Summerell: col. 6, 11-29**). The examiner interprets that the time period in Summerell could include a six month period.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell. One of ordinary skill in the art would have been motivated to combine these teachings because it helps patients see the progress toward a improved level of wellness (**Summerell: col. 6, 11-13**).

27. As per claim 34, the method of claim 12 is as described. Bond and Summerell do not teach wherein step (e), said evaluation of said code comprises reviewing said code submitted in step (d) for susceptibility to duplicative billing practices, unbundled billing practices, or a financial interest to the primary care physician that exceeds the scope of care provided.

Provost teaches wherein step (e), said evaluation of said code comprises reviewing said code submitted in step (d) for susceptibility to duplicative billing practices, unbundled billing practices, or a financial interest to the primary care physician that exceeds the scope of care provided (**Provost: col. 10, 35-52**).

The motivation to combine the teachings is the same as claim 12.

28. As per claim 35, the method of claim 1 is as described. Bond and Summerell do not teach wherein the medical request for medical services in step (b) is in relation to the treatment of a chronic condition requiring continuous care.

Provost does not explicitly teach wherein the medical request for medical services in step (b) is in relation to the treatment of a chronic condition requiring continuous care, but teaches wherein the medical request for medical services in step (b) is in relations to the treatment (Provost: col. 4, 7-16). The examiner interprets the diagnosis and treatment codes could include a medical request to the treatment of a chronic condition requiring continuous care.

The motivation to combine the teachings is the same as claim 1.

29. As per claim 36, the method of claim 35 is as described. Bond and Provost do not teach wherein the chronic condition is selected from a group consisting of diabetes, cancer, and Alzheimer's disease.

Summerell teaches wherein the chronic condition is selected from a group consisting of diabetes, cancer, and Alzheimer's disease (Summerell: col. 13, 18-45).

The motivation to combine the teaching sis the same as claim 1.

30. As per claim 37, the method of claim 35 is as described. Bond and Summerell do not teach wherein each specified clinical event assessed in step (c) is submitted as a single code every single time the specified clinical event is required until the specified clinical event is no longer required.

Provost teaches wherein each specified clinical event assessed in step (c) is submitted as a single code every single time the specified clinical event is required until the specified clinical event is no longer required (Provost: col. 4, 7-16).

The motivation to combine the teachings is the same as claim 1.

31. Claims 16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. (U.S. Patent No. 6,177,940) in view of Provost et al. (U.S. Patent No. 6,341,265) and further

in view of Summerell et al (U.S. Patent No. 5,937,387) and Wiggins (U.S. Patent No. 7,016,856).

32. As per claim 16, the method of claim 1 is as described. Bond, Provost, and Summerell do not teach wherein in step (a) said primary care physician is a member of a network of physicians contracted to render medical services on behalf of a health plan, health maintenance organization, or government sponsored health care program.

Wiggins teaches wherein in step (a) said primary care physician is a member of a network of physicians contracted to render medical services on behalf of a health plan, health maintenance organization, or government sponsored health care program (**Wiggins: col. 5, 35-42**).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bond in view of Provost with Summerell and Wiggins. One of ordinary skill in the art would have been motivated to combine these teachings to provide automated systems and methods for assisting an economic alliance of health care organizations in the management of financial risk inherent in the health care industry (**Wiggins: col. 1, 37-41**).

33. For claim 28, please see remarks and citations of claim 16.

Response to Arguments

34. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

35. Applicant argues that in regard to the submission of only a single CPT code, Provost discloses a form that may include multiple CPT codes, therefore it does not teach or suggest the

submission of only a single CPT code. Examiner disagrees. Provost teaches the submission of CPT codes to a remote server, and teaches that only a single CPT code can be submitted or multiple codes could be submitted, therefore, it encompasses the submission of only a single CPT code.

36. Applicant argues that the Examiner's interpretation that a medical technician is the same as a hospitalist or a case manager is inappropriate. Applicant argues that Provost is understood to teach a medical technician, who does not necessarily have proper training to determine payability of a code, submits the code to a remote server, wherein the remote server makes the actual evaluation; as such Provost's medical technician and Applicant's hospitalist or case manager cannot be considered to be the same. The Examiner disagrees. Examiner interprets the medical technician to be the same as a hospitalist or case manager; due to the medical technician making the evaluation of the submitted codes by using a system, therefore evaluating the single code submitted for clinical or financial appropriateness.

Conclusion

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheetal R. Rangrej whose telephone number is 571-270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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